



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

DATE: November 9, 2004

SUBJECT: Secondary Review of Contractor's (DynCorp Systems & Solutions LLC)
Efficacy Review for Maquat 710-HF,
EPA File Symbol 10324-RLO;
DP Barcode: D304662

FROM: Lorilyn M. Montford *Lm 11/10/04*
Efficacy Evaluation Team
Antimicrobials Division (7510C)

THRU: Nancy Whyte, Acting Team Leader *Nancy Whyte*
Efficacy Evaluation Team *November 10, 2004*
Antimicrobials Division (7510C)

TO: Velma Noble PM 31/Tracy Lantz
Regulatory Management Branch I
Antimicrobials Division (7510C)

APPLICANT: Mason Chemical Company
Arlington Heights, IL 60005

Formulation From Label:

<u>Active Ingredient(s)</u>	<u>% by wt.</u>
Octyl Decyl Dimethyl Ammonium Chloride	3.0%
Didecyl Dimethyl Ammonium Chloride.	1.5%
Diocetyl Dimethyl Ammonium Chloride.	1.5%
Alkyl (C ₁₄ , 50%, C ₁₂ , 40%; C ₁₆ , 10%) dimethyl benzyl ammonium chloride.	4.0%
Inert Ingredient(s).	90.0%
Total.	100.00%

I BACKGROUND

The product, Maquat 710-HF (EPA File Symbol 10324-RLO), is a new product. The applicant requested to register the product as a disinfectant (bactericide) and sanitizer (non-food contact surfaces) for use on hard, non-porous surfaces in household, institutional, industrial, commercial, food processing, animal care, and hospital or medical environments. The label claims that the product is effective for disinfecting at 781 ppm active quat (200 ppm active quat for sanitizing) in the presence of a 5% organic soil load. Studies were conducted at ATS Labs, located at 1285 Corporate Center Drive, Suite 110, Eagan, MN 55121.

This data package included a letter from the applicant to the Agency (dated June 6, 2004), ten studies (MRID Nos. 462920-04 through 462920-13), Statements of No Data Confidentiality Claims for all ten studies, and the proposed label.

II USE DIRECTIONS

The product is designed to be used for disinfecting hard, non-porous surfaces such as counter tops, stove tops, sinks, exterior surfaces of appliances, refrigerators and ice machines, non-food contact equipment, shelves, racks, carts, plumbing fixtures, tables, chairs, desks, bed frames, floors, walls, cabinets, doorknobs, garbage cans, picnic tables and outdoor furniture, telephones, showers, bathtubs, toilets, urinals, and kennels. Directions on the proposed label provided the following information regarding preparation and use of the product as a disinfectant: Prepare a use solution by adding 1 ounce of the product to 1 gallon of water (a 1:128 dilution). Apply the use solution using a cloth, mop, or mechanical spray device. Allow surfaces to remain wet for 10 minutes. Allow to air dry. For heavily soiled areas, a preliminary cleaning is required. Rinse food contact surfaces with potable water prior to reuse.

The product also is designed to be used for sanitizing hard, non-porous, non-food contact surfaces such as walls, floors, and tables. Directions on the proposed label provided the following information regarding preparation and use of the product as a sanitizer: Pre-clean surfaces. Prepare a use solution by adding 1 ounce of the product to 4 gallons of water (a 1:512 dilution). Apply the use solution using a cloth, mop, sponge, or spray foam generator, or by immersion. Allow surfaces to remain wet for 1 minute. Wipe dry or allow to air dry.

III AGENCY STANDARDS FOR PROPOSED CLAIMS

Disinfectants for Use on Hard Surfaces in Hospital or Medical Environments

The effectiveness of disinfectants for use on hard surfaces in hospital or medical environments must be substantiated by data derived using the AOAC Use-Dilution Method (for water soluble powders and liquid products) or the AOAC Germicidal Spray Products as Disinfectants Method (for spray products). Sixty carriers must be tested with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old, against *Salmonella choleraesuis* (ATCC 10708), *Staphylococcus aureus* (ATCC 6538), and *Pseudomonas aeruginosa* (ATCC 15442). To support products labeled as "disinfectants," killing on 59 out of 60 carriers is required to provide effectiveness at the 95% confidence level. These Agency standards are presented in DIS/TSS-1.

Sanitizers (For Non-Food Contact Surfaces)

The effectiveness of sanitizers for non-food contact surfaces must be supported by data that show that the product will substantially reduce the numbers of test bacteria on a treated surface. Testing requirements in EPA DIS/TSS-10 may be used. The test surface(s) should represent the type(s) of surfaces recommended for treatment on the label, i.e., porous or non-porous. Products that are represented as "one-step sanitizers" should be tested with an appropriate organic soil load, such as 5 percent serum. Tests should be performed with each of 3 product samples, representing 3 different product lots, one of which is at least 60 days old against *Staphylococcus aureus* (ATCC 6538) and either *Klebsiella pneumoniae* (aberrant, ATCC 4352) or *Enterobacter aerogenes* (ATCC 13048 or 15038). Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes. These Agency standards are presented in DIS/TSS-10.

There are cases where an applicant requests to make claims of effectiveness against additional microorganisms for a product that is to be used as a sanitizer for non-food contact surfaces. The DIS/TSS standards are silent on this matter. Confirmatory test standards would apply. Therefore, 2 product samples, representing 2 different product lots, should be tested against each additional microorganism. Results must show a bacterial reduction of at least 99.9 percent over the parallel control within 5 minutes.

Supplemental Claims

An antimicrobial agent identified as a "one-step" disinfectant or as effective in the presence of organic soil must be tested for efficacy with an appropriate organic soil load, such as 5 percent serum. These Agency standards are presented in DIS/TSS-2.

IV COMMENTS ON THE SUBMITTED EFFICACY STUDIES

1. MRID 462920-04 "AOAC Use-Dilution Method, Test Organism: *Pseudomonas aeruginosa* (ATCC 15442)" for Maquat 710-HF, by Sally Nada. Study conducted at ATS Labs. Study completion date – January 29, 2004. Project Number A01883.

This study was conducted against *Pseudomonas aeruginosa* (ATCC 15442). Three lots (Lot Nos. 1621-56, 1621-57, and 1621-58) of the product, Maquat 710-HF, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. All three product lots tested were at least 60 days old at the time of testing. A use solution was prepared by adding 10.0 mL of the product to 1270 mL of filter sterilized deionized water (a 1:128 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) stainless steel penicylinder carriers were immersed for 15 minutes in a 48-54 hour old suspension of the test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 35-37°C. Each carrier was exposed to 10 mL of the use solution for 10 minutes at 20±1°C. The carriers were transferred to 10 mL of Letheen Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

2. MRID 462920-05 "AOAC Use-Dilution Method, Test Organism: *Salmonella choleraesuis* (ATCC 10708)" for Maquat 710-HF, by Sally Nada. Study conducted at ATS Labs. Study completion date – January 29, 2004. Project Number A01885.

This study was conducted against *Salmonella choleraesuis* (ATCC 10708). Three lots (Lot Nos. 1621-56, 1621-57, and 1621-58) of the product, Maquat 710-HF, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. All three product lots tested were at least 60 days old at the time of testing. A use solution was prepared by adding 10.0 mL of the product to 1270 mL of filter sterilized deionized water (a 1:128 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) stainless steel penicylinder carriers were immersed for 15 minutes in a 48-54 hour old suspension of the test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 35-37°C. Each carrier was exposed to 10 mL of the use solution for 10 minutes at 20±1°C. The carriers were transferred to 10 mL of Lethen Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

3. MRID 462920-06 "AOAC Use-Dilution Method, Test Organism: *Staphylococcus aureus* (ATCC 6538)" for Maquat 710-HF, by Sally Nada. Study conducted at ATS Labs. Study completion date – January 29, 2004. Project Number A01884.

This study was conducted against *Staphylococcus aureus* (ATCC 6538). Three lots (Lot Nos. 1621-56, 1621-57, and 1621-58) of the product, Maquat 710-HF, were tested using the AOAC Use-Dilution Method as described in the AOAC Official Methods of Analysis, 15th Edition, 1990. All three product lots tested were at least 60 days old at the time of testing. A use solution was prepared by adding 6.0 mL of the product to 762 mL of filter sterilized deionized water (a 1:128 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Sixty (60) stainless steel penicylinder carriers were immersed for 15 minutes in a 48-54 hour old suspension of the test organism, at a ratio of 1 carrier per 1.0 mL broth. The carriers were dried for 40 minutes at 35-37°C. Each carrier was exposed to 10 mL of the use solution for 10 minutes at 20±1°C. The carriers were transferred to 10 mL of Lethen Broth with 0.07% Lecithin and 0.5% Tween 80 to neutralize. All subcultures were incubated for 48±4 hours at 35-37°C, and then examined for the presence or absence of visible growth. Controls included those for purity, sterility, viability, neutralization confirmation, and carrier population.

4. MRID 462920-07 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, Test Organism: *Listeria monocytogenes* (ATCC 19117)" for Maquat 710-HF, by Sally Nada. Study conducted at ATS Labs. Study completion date – February 12, 2004. Project Number A01907.

This study was conducted against *Listeria monocytogenes* (ATCC 19117). Two lots (Lot Nos. 1621-57 and 1621-58) of the product, Maquat 710-HF, were tested. The laboratory report referenced the Sanitizer Test from DIS/TSS-10 and the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-food Contact Surfaces (ASTM Method E1153). A use solution was prepared by adding 1.0 mL of the product to 511 mL of filter sterilized

deionized water (a 1:512 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass carriers, five per product lot, were inoculated with 0.01 mL of a 48±4 hour old suspension of the test organism. The carriers were dried for 20 minutes at roughly 35-37°C and a relative humidity of 40±2%. The carriers were transferred to individual jars and exposed to 5 mL of the use solution at 21.0°C for 1 minute. After exposure, 20.0 mL of Lethen Broth with 0.07% Lecithin and 0.5% Tween 80 was added to each jar to neutralize. The jars were rotated vigorously on an even plane for approximately 50 rotations. Within 30 minutes after addition of the neutralizer, 1.0 mL of the 10⁰ and 10⁻¹ dilutions of the neutralizer solution from each of the jars was plated in duplicate with Tryptic Soy Agar with 5% sheep blood. The neutralized subcultures were incubated for 48±4 hours at 35-37°C. Subcultures were stored at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier quantitation, purity, inoculum count, viability, neutralization confirmation, and sterility.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

5. MRID 462920-08 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, Test Organism: *Yersinia enterocolitica* (ATCC 23715)" for Maquat 710-HF, by Sally Nada. Study conducted at ATS Labs. Study completion date – February 12, 2004. Project Number A01908.

This study was conducted against *Yersinia enterocolitica* (ATCC 23715). Two lots (Lot Nos. 1621-57 and 1621-58) of the product, Maquat 710-HF, were tested. The laboratory report referenced the Sanitizer Test from DIS/TSS-10 and the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-food Contact Surfaces (ASTM Method E1153). A use solution was prepared by adding 1.0 mL of the product to 511 mL of filter sterilized deionized water (a 1:512 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass carriers, five per product lot, were inoculated with 0.01 mL of a 48±4 hour old suspension of the test organism. The carriers were dried for 20 minutes at roughly 35-37°C and a relative humidity of 40±2%. The carriers were transferred to individual jars and exposed to 5 mL of the use solution at 21.0°C for 1 minute. After exposure, 20.0 mL of Lethen Broth with 0.07% Lecithin and 0.5% Tween 80 was added to each jar to neutralize. The jars were rotated vigorously on an even plane for approximately 50 rotations. Within 30 minutes after addition of the neutralizer, 1.0 mL of the 10⁰ and 10⁻¹ dilutions of the neutralizer solution from each of the jars was plated in duplicate with Tryptic Soy Agar with 5% sheep blood. The neutralized subcultures were incubated for 48±4 hours at 35-37°C. Subcultures were stored at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier quantitation, purity, inoculum count, viability, neutralization confirmation, and sterility.

6. MRID 462920-09 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, Test Organism: *Salmonella enteritidis* (ATCC 4931)" for Maquat 710-HF, by Sally Nada. Study conducted at ATS Labs. Study completion date – February 11, 2004. Project Number A01904.

This study was conducted against *Salmonella enteritidis* (ATCC 4931). Two lots (Lot Nos. 1621-57 and 1621-58) of the product, Maquat 710-HF, were tested. The laboratory report referenced the Sanitizer Test from DIS/TSS-10 and the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-food Contact Surfaces (ASTM Method E1153). A use solution was prepared by adding 1.0 mL of the product to 511 mL of filter sterilized deionized water (a 1:512 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass carriers, five per product lot, were inoculated with 0.01 mL of a 48±4 hour old suspension of the test organism. The carriers were dried for 20 minutes at 35-37°C and a relative humidity of 40±2%. The carriers were transferred to individual jars and exposed to 5 mL of the use solution at 21.0°C for 1 minute. After exposure, 20.0 mL of Lethen Broth with 0.07% Lecithin and 0.5% Tween 80 was added to each jar to neutralize. The jars were rotated vigorously on an even plane for approximately 50 rotations. Within 30 minutes after addition of the neutralizer, 1.0 mL of the 10⁰ and 10⁻¹ dilutions of the neutralizer solution from each of the jars was plated in duplicate with Tryptic Soy Agar with 5% sheep blood. The neutralized subcultures were incubated for 48±4 hours at 35-37°C. Subcultures were stored at 2-8°C for 2 days prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier quantitation, purity, inoculum count, viability, neutralization confirmation, and sterility.

7. MRID 462920-10 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, Test Organism: *Salmonella choleraesuis* (ATCC 10708)" for Maquat 710-HF, by Sally Nada. Study conducted at ATS Labs. Study completion date – February 9, 2004. Project Number A01906.

This study was conducted against *Salmonella choleraesuis* (ATCC 10708). Two lots (Lot Nos. 1621-57 and 1621-58) of the product, Maquat 710-HF, were tested. The laboratory report referenced the Sanitizer Test from DIS/TSS-10 and the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-food Contact Surfaces (ASTM Method E1153). A use solution was prepared by adding 1.0 mL of the product to 511 mL of filter sterilized deionized water (a 1:512 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass carriers, five per product lot, were inoculated with 0.01 mL of a 48±4 hour old suspension of the test organism. The carriers were dried for 20 minutes at 35-37°C and a relative humidity of 40±2%. The carriers were transferred to individual jars and exposed to 5 mL of the use solution at 21.0°C for 1 minute. After exposure, 20.0 mL of Lethen Broth with 0.07% Lecithin and 0.5% Tween 80 was added to each jar to neutralize. The jars were rotated vigorously on an even plane for approximately 50 rotations. Within 30 minutes after addition of the neutralizer, 1.0 mL of the 10⁰ and 10⁻¹ dilutions of the neutralizer solution from each of the jars was plated in duplicate with Tryptic Soy Agar with 5% sheep blood. The neutralized subcultures were incubated for 48±4 hours at 35-37°C. Subcultures were stored at 2-8°C for 1 day prior to examination. Following incubation and storage, the subcultures were

examined for the presence or absence of visible growth. Controls included those for carrier quantitation, purity, inoculum count, viability, neutralization confirmation, and sterility.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

8. MRID 462920-11 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, Test Organism: *Escherichia coli* O157:H7 (ATCC 35150)" for Maquat 710-HF, by Sally Nada. Study conducted at ATS Labs. Study completion date – February 25, 2004. Project Number A01903.

This study was conducted against *Escherichia coli* O157:H7 (ATCC 35150). Two lots (Lot Nos. 1621-57 and 1621-58) of the product, Maquat 710-HF, were tested. The laboratory report referenced the Sanitizer Test from DIS/TSS-10 and the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-food Contact Surfaces (ASTM Method E1153). A use solution was prepared by adding 1.0 mL of the product to 511 mL of filter sterilized deionized water (a 1:512 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass carriers, five per product lot, were inoculated with 0.03 mL of a 48±4 hour old suspension of the test organism. The carriers were dried for 20 minutes at 35-37°C and a relative humidity of 40±2%. The carriers were transferred to individual jars and exposed to 5 mL of the use solution at 21.0°C for 1 minute. After exposure, 20.0 mL of Lethen Broth with 0.07% Lecithin and 0.5% Tween 80 was added to each jar to neutralize. The jars were rotated vigorously on an even plane for approximately 50 rotations. Within 30 minutes after addition of the neutralizer, 1.0 mL of the 10⁰ and 10⁻¹ dilutions of the neutralizer solution from each of the jars was plated in duplicate with Tryptic Soy Agar with 5% sheep blood. The neutralized subcultures were incubated for 48±4 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier quantitation, purity, inoculum count, viability, neutralization confirmation, and sterility.

Note: The applicant provided the data for a failed trial performed on January 30, 2004. In that trial, the carrier quantitation control was below the acceptance criterion (i.e., geometric mean of at least 2.0 x 10⁴ CFU/carrier). Thus, the test was invalid. These data were not used to evaluate efficacy of the product. See Attachment I of the laboratory study.

9. MRID 462920-12 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, Test Organism: *Shigella dysenteriae* (ATCC 11835)" for Maquat 710-HF, by Sally Nada. Study conducted at ATS Labs. Study completion date – February 24, 2004. Project Number A01905.

This study was conducted against *Shigella dysenteriae* (ATCC 11835). Two lots (Lot Nos. 1621-57 and 1621-58) of the product, Maquat 710-HF, were tested. The laboratory report referenced the Sanitizer Test from DIS/TSS-10 and the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-food Contact Surfaces (ASTM Method E1153). A use solution was prepared by adding 1.0 mL of the product to 511 mL of filter sterilized deionized water (a 1:512 dilution). Fetal bovine serum was added to the culture to achieve a 5%

organic soil load. Ten (10) glass carriers, five per product lot, were inoculated with 0.03 mL of a 48±4 hour old suspension of the test organism. The carriers were dried for 20 minutes at 35-37°C and a relative humidity of 40±2%. The carriers were transferred to individual jars and exposed to 5 mL of the use solution at 21.0°C for 1 minute. After exposure, 20.0 mL of Lethen Broth with 0.07% Lecithin and 0.5% Tween 80 was added to each jar to neutralize. The jars were rotated vigorously on an even plane for approximately 50 rotations. Within 30 minutes after addition of the neutralizer, 1.0 mL of the 10⁰ and 10⁻¹ dilutions of the neutralizer solution from each of the jars was plated in duplicate with Tryptic Soy Agar with 5% sheep blood. The neutralized subcultures were incubated for 48±4 hours at 35-37°C. Following incubation, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier quantitation, purity, inoculum count, viability, neutralization confirmation, and sterility.

Note: The applicant provided the data for a failed trial performed on February 5, 2004. In that trial, the carrier quantitation control was below the acceptance criterion (i.e., geometric mean of at least 2.0 x 10⁴ CFU/carrier). Thus, the test was invalid. These data were not used to evaluate efficacy of the product. See Attachment I of the laboratory study.

10. MRID 462920-13 "Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-Food Contact Surfaces, Test Organisms: *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352)" for Maquat 710-HF, by Sally Nada. Study conducted at ATS Labs. Study completion date – December 15, 2003. Project Number A01803.

This study was conducted against *Staphylococcus aureus* (ATCC 6538) and *Klebsiella pneumoniae* (ATCC 4352). Three lots (Lot Nos. 1621-56, 1621-57 and 1621-58) of the product, Maquat 710-HF, were tested. The laboratory report referenced the Sanitizer Test from DIS/TSS-10 and the Standard Test Method for Efficacy of Sanitizers Recommended for Inanimate Non-food Contact Surfaces (ASTM Method E1153). A use solution was prepared by adding 1.0 mL of the product to 511 mL of filter sterilized deionized water (a 1:512 dilution). Fetal bovine serum was added to the culture to achieve a 5% organic soil load. Ten (10) glass carriers, five per product lot per organism, were inoculated with 0.01 mL of a 48±4 hour old suspension of the test organism. The carriers were dried for 30 minutes at 35-37°C and a relative humidity of 40±2%. The carriers were transferred to individual jars and exposed to 5 mL of the use solution at 21.0°C for 1 minute. After exposure, 20.0 mL of Lethen Broth with 0.07% Lecithin and 0.5% Tween 80 was added to each jar to neutralize. The jars were rotated vigorously on an even plane for approximately 50 rotations. Within 30 minutes after addition of the neutralizer, 1.0 mL of the 10⁰ and 10⁻¹ dilutions of the neutralizer solution from each of the jars was plated in duplicate with Tryptic Soy Agar with 5% sheep blood. The neutralized subcultures were incubated for 48±4 hours at 35-37°C. Subcultures were stored at 2-8°C for 3 days prior to examination. Following incubation and storage, the subcultures were examined for the presence or absence of visible growth. Controls included those for carrier quantitation, purity, inoculum count, viability, neutralization confirmation, and sterility.

Note: Protocol deviations/amendments reported in the study were reviewed and found to be acceptable.

V RESULTS

MRID Number	Organism	No. Exhibiting Growth/ Total No. Tested			Carrier Population (CFU/ carrier)
		Lot No. 1621-56	Lot No. 1621-57	Lot No. 1621-58	
462920-04	<i>Pseudomonas aeruginosa</i>	0/60	0/60	0/60	1.26×10^5
462920-05	<i>Salmonella choleraesuis</i>	0/60	0/60	0/60	6.3×10^5
462920-06	<i>Staphylococcus aureus</i>	1/60	1/60	0/60	1.40×10^5

MRID Number	Organism	Lot No.	Average No. Surviving	Microbes Initially Present	Percent Reduction
			(CFU/carrier)		
462920-07	<i>Listeria monocytogenes</i>	1621-57	<30.2	3.63 x 10 ⁵	>99.9
		1621-58	<30.2	3.63 x 10 ⁵	>99.9
462920-08	<i>Yersinia enterocolitica</i>	1621-57	<30.2	9.3 x 10 ⁴	>99.9
		1621-58	<30.2	9.3 x 10 ⁴	>99.9
462920-09	<i>Salmonella enteritidis</i>	1621-57	<30.2	4.27 x 10 ⁵	>99.9
		1621-58	<30.2	4.27 x 10 ⁵	>99.9
462920-10	<i>Salmonella choleraesuis</i>	1621-57	<30.2	9.77 x 10 ⁴	>99.9
		1621-58	<30.2	9.77 x 10 ⁴	>99.9
462920-11	<i>Escherichia coli</i> O157:H7	1621-57	<30.2	3.63 x 10 ⁵	>99.9
		1621-58	<30.2	3.63 x 10 ⁵	>99.9
462920-12	<i>Shigella dysenteriae</i>	1621-57	<30.2	7.94 x 10 ⁵	>99.9
		1621-58	<30.2	7.94 x 10 ⁵	>99.9
462920-13	<i>Staphylococcus aureus</i>	1621-56	<30.2	3.24 x 10 ⁶	>99.9
		1621-57	<30.2	3.24 x 10 ⁶	>99.9
		1621-58	<30.2	3.24 x 10 ⁶	>99.9
	<i>Klebsiella pneumoniae</i>	1621-56	<36.3	1.12 x 10 ⁶	>99.9
		1621-57	<69.2	1.12 x 10 ⁶	>99.9

MRID Number	Organism	Lot No.	Average No. Surviving	Microbes Initially Present	Percent Reduction
			(CFU/carrier)		
		1621-58	<93.3	1.12 x 10 ⁶	>99.9

VI CONCLUSIONS

1. The submitted efficacy data support the use of the product, Maquat 710-HF, as a disinfectant with bactericidal activity against the following microorganisms on hard, non-porous surfaces in the presence of a 5% organic soil load (fetal bovine serum) for a contact time of 10 minutes at a 1:128 dilution:

<i>Pseudomonas aeruginosa</i>	MRID No. 462920-04
<i>Salmonella choleraesuis</i>	MRID No. 462920-05
<i>Staphylococcus aureus</i>	MRID No. 462920-06

Killing was observed in the subcultures of at least 59 of the 60 carriers tested against three lots of the product. All of the product lots tested were at least 60 days old at the time of testing. Dried carrier counts were at least 10^4 . Neutralization confirmation testing showed positive growth of the organisms. Viability controls were positive for growth. Purity controls were reported as pure. Sterility controls did not show growth.

2. The submitted efficacy data support the use of the product, Maquat 710-HF, as a sanitizing rinse on hard, non-porous, non-food contact surfaces in the presence of a 5% organic soil load (fetal bovine serum) against the following microorganisms for a contact time of 1 minute at a 1:512 dilution:

<i>Escherichia coli</i> O125:H7	MRID No. 460920-11 ✓ 46292011 T.K.L.
<i>Listeria monocytogenes</i>	MRID No. 462920-07 ✓
<i>Salmonella choleraesuis</i>	MRID No. 460920-10 ✓ 46292010 T.K.L.
<i>Salmonella enteritidis</i>	MRID No. 462920-09 ✓
<i>Shigella dysenteriae</i>	MRID No. 460920-12 ✓ 46292012 T.K.L.
<i>Yersinia enterocolitica</i>	MRID No. 462920-08 ✓

A 99.9% reduction in population was observed. The carrier quantitation controls met the acceptance criterion (i.e., geometric mean of at least 2.0×10^4 CFU/carrier). Neutralization confirmation testing showed growth of the microorganisms within $\pm 1 \log_{10}$ of the numbers control. Viability controls were positive for growth. Purity controls were pure. Sterility controls did not show growth.

3. The submitted efficacy data support the use of the product, Maquat 710-HF, as a sanitizing rinse on hard, non-porous, non-food contact surfaces in the presence of a 5% organic soil load (fetal bovine serum) against the following microorganisms for a contact time of 1 minute at a 1:512 dilution:

Klebsiella pneumoniae

MRID No. 460920-13

46292013 T.K.L.

Staphylococcus aureus

MRID No. 460920-T3

46292013 T.K.L.

The carrier quantitation controls met the acceptance criterion (i.e., geometric mean of at least 2.0×10^4 CFU/carrier). Neutralization confirmation testing showed growth of the microorganisms within $\pm 1 \log_{10}$ of the numbers control. Viability controls were positive for growth. Purity controls were pure. Sterility controls did not show growth.

VII RECOMMENDATIONS

1. The proposed label claims that the product, Maquat 710-HF, is an effective disinfectant on hard, non-porous, non-food contact surfaces against *Pseudomonas aeruginosa*, *Salmonella choleraesuis*, and *Staphylococcus aureus* when used at a 1:128 dilution in the presence of 5% serum for a contact time of 10 minutes. This claim is supported by the applicant's data.
2. The proposed label claims that the product, Maquat 710-HF, is an effective sanitizer on hard, non-porous, non-food contact surfaces against the following microorganisms when used in the presence of 5% organic soil for a contact time of 1 minute at a 1:512 dilution:

Escherichia coli O125:H7

MRID No. 460920-11

Listeria monocytogenes

MRID No. 462920-07

Salmonella choleraesuis

MRID No. 460920-10

Salmonella enteritidis

MRID No. 462920-09

Shigella dysenteriae

MRID No. 460920-12

Yersinia enterocolitica

MRID No. 462920-08

Same
corrections
as above

These claims are supported the applicant's data.

3. The proposed label claims that the product, Maquat 710-HF, is an effective sanitizer on hard, non-porous, non-food contact surfaces against *Staphylococcus aureus* and *Klebsiella pneumoniae* when used in the presence of 5% organic soil for a contact time of 1 minute at a 1:512 dilution. This claim is supported by the applicant's data.

4. The proposed label [see page 2 of the proposed label; left side; thirteenth item] claims that the product kills "viruses associated with the Avian hatchery industry, poultry, swine and livestock premises, laboratory animal facilities and kennels." The proposed label [see page 5 of the proposed label; right column] also claims that the product may be used as a disinfectant and virucide of poultry/turkey equipment, swine quarters, animal quarters, and kennels. The applicant has not provided efficacy data to support any claims regarding use of the product as a virucide. The applicant must delete all references to use of the product as a virucide from the product label.

5. Since the applicant has not provided residual efficacy data, it is requested that the following claim [see page 2 of the proposed label; right column; ninth item;] be removed from the product label: "This product inhibits bacterial growth on moist surfaces and deodorizes by killing microorganisms that cause offensive odors."

6. The proposed label indicates that the product may be used on footbaths [see page 3 of the proposed label; left column]. The applicant needs to remove this item from the label, or provide specific instructions on how to use the product to disinfect/sanitize footbath surfaces. Efficacy data for *Candida albicans* has not been provided.

7. The proposed label indicates that the product may be used on picnic tables and outdoor furniture [see page 3 of the proposed label; right column]. These products may be manufactured with wood and upholstery, which are porous materials. It is requested that the label be revised to indicate use of the product on "Tables and non-wooden picnic tables" and "Outdoor (patio) furniture, except cushions and wood frames."

8. The proposed label indicates that the product kills mold and mildew and may be used to control the growth of mold and mildew [see page 4 of the proposed label; right column]. The proposed label also indicates that the product is effective against odor causing fungi [see page 7 of the proposed label; left column]. The applicant has not provided data to support any claims regarding use of the product as a mildewstat or fungicide. This claim is to be removed from the proposed label unless the applicant can provide information to support this.

9. The proposed label claims that the product may be used to control small flies on non-food contact surfaces [see page 1 (right column) and page 5 (left column) of the proposed label]. The data package provided did not include data to support these claims. Therefore, the claim is to be removed from the proposed label unless the applicant can provide information to support this.

10. The applicant needs to make the following changes to the proposed label:

- On page 7 under the "Water and Smoke Damage Restoration" section, add in bold face **Water Damage Restoration:** before the text beginning "Effective against odor causing bacteria and fungi for home" The water damage restoration section is referred to in other parts of the label, yet is not clearly marked.
- On page 7 under the "For rotary floor machines" section, change "at he rate of" to read "at the rate of."